IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

| | | |
|---|---|---|
| SIGHT SCIENCES, INC.,<br><br>Plaintiff,<br><br>v.<br><br>IVANTIS, INC., ALCON RESEARCH LLC, ALCON VISION, LLC AND ALCON INC.,<br><br>Defendants. | ) | C. A. No.: 21-1317-GBW-SRF<br><br>**JURY TRIAL DEMANDED**<br><br>[redacted]<br><br>[redacted]<br><br>**Redacted - Public Version Filed on: October 23, 2023** |

**PLAINTIFF SIGHT SCIENCES, INC.'S CONCISE STATEMENTS OF FACTS IN SUPPORT OF ITS MOTIONS FOR SUMMARY JUDGMENT**

Pursuant to Paragraph 14(b) of the Scheduling Order (D.I. 93), Plaintiff Sight Sciences, Inc. submits its concise statements of facts ("SOF") in support of its motions for summary judgment:

1. Concise Statement of Facts in Support of Summary Judgment Motion No. 1 ("SOF1," Ex. 1).

2. Concise Statement of Facts in Support of Summary Judgment Motion No. 2 ("SOF2," Ex. 2).

3. Concise Statement of Facts in Support of Summary Judgment Motion No. 3 ("SOF3," Ex. 3).

Sight Sciences relies on SOF1 and SOF2 in support of Summary Judgment Motion No. 4.

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Dated: October 12, 2023

*Attorneys for Sight Sciences, Inc.*

30862007.1

# EXHIBIT 1

[redacted]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

| | | |
|---|---|---|
| SIGHT SCIENCES, INC.,<br><br>Plaintiff,<br><br>v.<br><br>IVANTIS, INC., ALCON RESEARCH LLC, ALCON VISION, LLC AND ALCON INC.,<br><br>Defendants. | ) | C. A. No.: 21-1317-GBW-SRF<br><br>**JURY TRIAL DEMANDED**<br><br>[redacted] |

**CONCISE STATEMENT OF FACTS IN SUPPORT OF**
**SIGHT SCIENCES, INC.'S MOTION FOR SUMMARY JUDGMENT NO. 1**

1. The Accused Products are the Hydrus® Microstent ("Hydrus") and the accompanying Hydrus Microstent Delivery System and Instructions for Use ("IFU"). (D.I. 59, ¶¶41-76.)

2. The Hydrus is a support. (*E.g.*, Ex. 1 (IVANTIS_SS_00041120), 41120.) It [redacted] (*Id.* (emphasis added); Ex. 84 (IVANTIS_SS_00063113), 63124 [redacted]); Ex. 83 (SGHT016815), FIG. 2(a) (showing dilation of Schlemm's Canal along cross-section of implanted Hydrus); Ex. 11 (IVANTIS_SS_00021965), 21990, 21992, 22149, 22159, 22184 [redacted]); Ex. 19 (00001276), 1280 ([redacted] Ex. 21 (00415663), 415668 ([redacted] Ex. 9 (Kimball Tr.) at 139:23-34 [redacted]

[redacted]); Ex. 27 (Schieber Tr.) at 53:3-4 [redacted]

[redacted]))

3. The Hydrus is a device. (*E.g.*, Ex. 1 (IVANTIS_SS_00041120-40), 41120, 41122.) The Hydrus is a "crescent-shaped implantable microstent pre-loaded onto a hand-held delivery system" and is supplied with IFU. (Ex. 1 at IVANTIS_SS_00041120; *see also* Ex. 2 (RFA Responses), No. 20 (admitting that "Hydrus is sold to physicians with instructions for use"); Ex. 3 (Abraham Tr.) at 129:22-130:9 (explaining that each unit sold includes the delivery system with the Hydrus stent loaded in it, along with IFU and any labeling); Ex. 4 (Marshall Tr.) 73:17-22; Ex. 5 (IVANTIS_SS_00001009); Ex. 6 (IVANTIS_SS_00000998).)

4. The Hydrus is "indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild to moderate primary open-angle glaucoma (POAG)." (D.I. 77, ¶42; Ex. 2 (RFA Responses), No. 1; *see also* Ex. 7 (Iwach Tr.) 41:14-18 ("Q. And that it's indicated for the reduction of intraocular pressure in adult patients with mild to moderate primary open-angle glaucoma, correct? A. Correct."), 90:9-13 ("as that Hydrus is implanted in a patient with open-angle glaucoma"); Ex. 1 at IVANTIS_SS_00041122.)

5. The Hydrus has fenestrations. (Ex. 7 (Iwach Tr.) at 48:1-3 ("Q. But you'd know and agree that the Hydrus Microstent has windows, correct? A. It -- it has fenestrations."); D.I. 77, ¶44 (admitting that the Hydrus has "'windows' to provide outflow pathways for aqueous humor"); Ex. 2 (RFA Responses), No. 5 ("Defendants admit that Hydrus has windows."); Ex. 1 at IVANTIS_SS_00041120.)

6. The Hydrus is inserted lengthwise into a lumen of Schlemm's canal. (Ex. 7 (Iwach Tr.) at 43:7-44:5 (the Hydrus is inserted along the length of Schlemm's canal and occupies a

portion of the canal); Ex. 8 (Hadba Tr.) at 122:6-18; Ex. 1 at IVANTIS_SS_00041125-26; Ex. 17 (IVANTIS_SS_00056891-917) at 56896-97.)

7. Upon implantation, the Hydrus Microstent has points of discontinuous contact along both cross-sectional and longitudinal perimeters of Schlemm's Canal. (*See* Ex. 18 (Downs Op.), ¶¶112-116; *see also* Ex. 48, IVANTIS_SS_00010691 at 10695, 10739; *see also* Ex. 83, SGHT0168157).

8. The Hydrus is pre-loaded onto an introducer comprising a pusher. (D.I. 77, ¶46 (admitting that the Hydrus is "pre-loaded onto a hand held delivery system"); Ex. 2 (RFA Responses), Nos. 11-13 (admitting that "Hydrus is implanted into the eye using a hand-held delivery system," "the Hydrus is pre-loaded onto a hand-held delivery system," and "the Hydrus is interlocked on a pusher assembly and implanted into the eye using a hand-held delivery system"); Ex. 7 (Iwach Tr.) at 44:6-9; Ex. 3 (Abraham Tr.) at 129:22-130:9; Ex. 8 (Hadba Tr.) at 161:6-162:10; Ex. 1 at IVANTIS_SS_00041120-22; Ex. 16 (IVANTIS_SS_00016417).) The Hydrus is delivered "through a stainless steel [tubular] cannula into the target site in the eye." (*See* Ex. 1 at IVANTIS_SS_00041120-21; *see also* D.I. 77, ¶46; Ex. 8 (Hadba Tr.) at 105:7-11 ("A. [The delivery system] has a cannula at the end, yes. Q. Is that cannula tubular? A. It is."); Ex. 1 at IVANTIS_SS_00041120-22.)

9. The "Hydrus is composed of nitinol, a shape memory alloy" with "properties of flexibility, strength, and biocompatibility." (Ex. 2 (RFA Responses), No. 3; *see also* Ex. 7 (Iwach Tr.) 46:21-47:6, 72:7-16; Ex. 8 (Hadba Tr.) 106:4-16, 110:25-111:3.)

10. The Hydrus is laser cut from a single piece of nitinol tubing to form an arcuate support. (Ex. 7 (Iwach Tr.) 55:12-19; Ex. 9 (Kimball Tr.) 62:4-6; Ex. 10

(IVANTIS_SS_00019129) at 19197; Ex. 11 (IVANTIS_SS_00021965) at 22013; Ex. 1 at IVANTIS_SS_00041120; *see also* Ex. 12 (IVANTIS_SS_00000429) at 430.)

11. The Hydrus support has "alternating 'spines' for structural support and 'windows' to provide outflow pathways." (D.I. 77, ¶44; Ex. 1 at IVANTIS_SS_00041120.) The alternating spine-window design of the Hydrus results in undulations (i.e., uneven edges) along its length. (Ex. 7 (Iwach Tr.) at 61:19-68:9 (offering no opinion as to this limitation); *see also generally* Ex. 13 (Iwach Reb.) (offering no opinion regarding "fluted edges"); Ex. 14 (IVANTIS_SS_00057727) at 57732-33; Ex. 15 (IVANTIS_SS_00000033) at 34.)

12. When disposed within a cylindrical section of the lumen of the canal having an internal wall surface area C, the Hydrus contacts less than 30% of C. (Ex. 18 (Downs Op.), ¶¶117-138, 140-143; Ex. 7 (Iwach Tr.) at 196:4-197:2 (confirming that he has no opinion on this limitation).

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Dated: October 12, 2023

*Attorneys for Sight Sciences, Inc.*

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# EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

| | | |
|---|---|---|
| SIGHT SCIENCES, INC.,<br><br>Plaintiff,<br><br>v.<br><br>IVANTIS, INC., ALCON RESEARCH LLC, ALCON VISION, LLC AND ALCON INC.,<br><br>Defendants. | ) | C. A. No.: 21-1317-GBW-SRF<br><br>**JURY TRIAL DEMANDED** |

**CONCISE STATEMENT OF FACTS IN SUPPORT OF**
**SIGHT SCIENCES, INC.'S MOTION FOR SUMMARY JUDGMENT NO. 2**

1. The Accused Products are the Hydrus® Microstent ("Hydrus") and the accompanying Hydrus Microstent Delivery System and Instructions for Use ("IFU"). (D.I. 59, ¶¶41-76.)

2. The Hydrus has a cross-sectional diameter of 292 micrometers along its major axis and 185 micrometers along its minor axis. (Ex. 18 (Downs Op.) ¶¶239-240; Ex. 2 (RFA Responses), No. 8 ("Defendants admit that Hydrus has major and minor axes of 292 µm and 185 µm, respectively."); Ex. 7 (Iwach Tr.) 48:15-24; Ex. 17 (IVANTIS_SS_00056891).)

3. Hydrus [redacted]

4. Hydrus' windows [redacted]

[redacted]

5. Ivantis represented to the FDA [redacted]

[redacted]

);

*see also* Ex. 25 (IVANTIS_SS_00023750) at 23768.)

6. Hydrus leaves [redacted]

[redacted]

[redacted]

7. [redacted]

[redacted]

8. Hydrus patients [redacted]

[redacted]; Ex. 33 (SGHT0179706) (study concluding that, when compared to phacoemulsification and iStent inject, device obstruction was significantly more common in patients receiving phacoemulsification and Hydrus, with 8 patients (14%) that received the Hydrus implant exhibiting iris adhesions to the inlet of the device).)

9. Defendants' expert, Dr. Tanna, [redacted] ¶144

(IVANTIS_SS_00172874) at 172932-33 [redacted]

[redacted].)

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Dated: October 12, 2023

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# EXHIBIT 3

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

| | | |
|---|---|---|
| SIGHT SCIENCES, INC.,<br><br>Plaintiff,<br><br>v.<br><br>IVANTIS, INC., ALCON RESEARCH LLC, ALCON VISION, LLC AND ALCON INC.,<br><br>Defendants. | ) | C. A. No.: 21-1317-GBW-SRF<br><br>**JURY TRIAL DEMANDED** |

**CONCISE STATEMENT OF FACTS IN SUPPORT OF**
**SIGHT SCIENCES, INC.'S MOTION FOR SUMMARY JUDGMENT NO. 3**

1. Defendants served their initial invalidity contentions on September 1, 2022 identifying iStent as alleged prior art to certain Asserted Claims of the '482, '443, '361, and '742 patents. (Ex. 35 (Initial Invalidity Contentions) at 8, 15-17.) Defendants allege therein that iStent was first used publicly "at least as early as July 2004." (*Id.* at 8.)

2. Defendants subsequently served their Corrected First Supplemental Initial Invalidity Contentions on October 6, 2022 identifying iStent as alleged prior art to certain Asserted Claims of the newly asserted '328 patent. (Ex. 36 (First Suppl. Invalidity Contentions) at 17.)

3. In the accompanying claim charts, Ivantis argued that "[t]he Glaukos iStent® ("iStent") was undergoing public clinical trials in the United States at least as early as July 2004, the public use of which qualifies as prior art to the [Asserted Patents] under at least 35 U.S.C. §§ 102(a) and (b) (pre-AIA). *See, e.g.*, Bahler at 993 (describing clinical trial ongoing in the United States); Samuleson [sic] at 459, 462 (published clinical trial results from clinical trial in which patients began enrolling in April 2005); NCT00323284 (clinicaltrials.gov study identifier)." (Ex. 37 (Initial Invalidity Contentions, Exhibit 443-A13) at 1.)

4. Ivantis identified the following publications as support for the alleged prior art

status and public disclosures related to iStent: Bahler et al., Am. J. Ophthalmol. 138:988–94 (2004), DOI:10.1016/j.ajo.2004.07.035 (*See* Ex. 35 (Initial Invalidity Contentions) at 8), and Samuelson et al, Am. Academy of Ophthalmol. 118:459-467 (2011), DOI:10.1016/j.ophtha.2010.07.007 (*See*, *e.g.*, Ex. 37 (Initial Invalidity Contentions, Exhibit 443-A13) at 1.)

5. In the opening expert report of Dr. Tanna on invalidity of the Asserted Patents, Dr. Tanna cited additional publications that describe aspects of the iStent device, and that Dr. Tanna alleges support his claims that the Asserted Patents are anticipated and/or obvious based on iStent, including: Samuelson 2004, (Ex. 38), Samuelson2 (Ex. 39), and the iStent Directions for Use (Ex. 40). (*See*, *e.g.*, Ex. 41 (Tanna Op.) at 191-192); Ex. 42 (Ex. A to Tanna Op.) at 2.).) However, Dr. Tanna did not substantively cite to or rely on Samuelson 2004 in his invalidity analysis related to iStent. (*See* Ex. 41 at 242-288, 359-363, 491-503, 525-530, and 562-569.)

6. Glaukos did not receive Pre-Marketing Approval from the FDA for iStent until June 25, 2012. (Ex. 43 (iStent Pre-Marketing Approval letter from the FDA, dated June 25, 2012 (SGHT0170452-57)).)

7. Dr. Tanna admits that he did not provide any evidence showing that the iStent was available for commercial sale in the United States before June 26, 2006. (Ex. 44 (Tanna Tr.) 226:9-14 ("Q. Have you provided any evidence in your reports to verify that the iStent was available for sale prior to 2006? A. I don't -- no, I don't think there's any -- any evidence that I've provided in my report.").)

8. Dr. Tanna admits that the iStent was not subject to a commercial sale in the United States before June 26, 2006. (Ex. 44 (Tanna Tr.) 226:15-19 ("Q. Okay. So the iStent was not on commercial sale in the United States prior to 2006, correct? … THE WITNESS: That is correct.").)

9. Dr. Tanna admits that there were no public uses of the iStent in the United States before June 26, 2006. (Ex. 44 (Tanna Tr.) 226:21-227:8 ("Q. And was the iStent available publicly – were there public prior uses before 2006, June 2006, in the United States? A. Define – [Objection] THE WITNESS: Define "public prior use." BY MS. RHYU: Q: Public prior use is a use that's open to the public and is not an experimental use. A. In the United States, no, there was not public prior use by 2006.").)

10. Dr. Tanna also admits that availability for clinical trials does not equate to public availability. (Ex. 44 (Tanna Tr.) 258:13-18 ("Q. Is availability for clinical trials public availability according to your definition? … THE WITNESS: I -- I don't think so, no.").)

11. Dr. Tanna admits that he has no evidence the Directions for Use ("DFU") were available before June 26, 2006. (Ex. 44 (Tanna Tr.) 229:8-14 ("Q. These directions for use, do you have any evidence to support the proposition that these directions for use were available prior to June 26, 2006? … THE WITNESS: No, I don't personally know that it was.").)

12. Dr. Tanna admits that Samuelson2 was published after June 26, 2006, in 2011, and is not prior art to the Asserted Patents. (Ex. 44 (Tanna Tr.) 232:21-233:4 ("Q. … I've marked Exhibit 18 the Samuelson 2 reference… A. Thank you. So yeah. Of course, this is not prior art. It was published in 2011.").)

13. Dr. Parrish, one of Sight's experts, also testified that clinical trial data is protected by federal law and access is not granted to the public. Accordingly, the results of the iStent clinical trial would not have been publicly available on June 26, 2006. (Ex. 59 (Parrish Tr.) 155:16-156:16 ("Q. Do you understand that persons of ordinary skill in the art are deemed to be aware of public uses to the extent something is defined as a public use? A. I'm aware that clinical trial data is protected by federal law, and that access to that information is not granted to the public. The

determination of the safety and efficacy of devices under trial are reviewed by a safety monitoring committee. So I don't believe a person of ordinary skill in the art would have access to the information, knowing whether or not this was doable or not. Q. Is it your opinion that the iStent clinical trials are not prior art because clinical trial data is maintained as confidential? …THE WITNESS: My understanding is that the results of a clinical trial relating to the efficacy of the iStent was not publicly available on June 26th, 2006.").)

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Dated: October 12, 2023

30860347.1

**CERTIFICATE OF SERVICE**

I, Melanie K. Sharp, Esquire, hereby certify that on October 12, 2023, I caused to be electronically filed a true and correct copy of Plaintiff Sight Sciences, Inc.'s Concise Statements of Facts in Support of its Motions for Summary Judgment with the Clerk of the Court using CM/ECF, which will send notification to the following counsel of record:

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I further certify that on October 12, 2023, I caused a copy of the foregoing document to be served on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

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